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Marco Mastrodonato

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MARSHALL, GERSTEIN & BORUN LLP
233 SOUTH WACKER DRIVE
6300 SEARS TOWER
CHICAGO, IL 60606-6357

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,023	Applicant(s) MASTRODONATO, MARCO	
	Examiner ERIC S. OLSON	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 18, 19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 10 and 12 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11, 13-15, 18, 19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/22/2007, 4/7/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This application is a national stage application of PCT/EP04/11228, filed October 7, 2004, which claims priority to foreign application IT MI2003A001941, filed October 9, 2003. Claims 1-15, 18, 19, and 21-26 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted April 7, 2006 is acknowledged wherein claims 3, 5, 6, 13, 18, and 19 are amended, claims 16, 17, and 20 are cancelled, and new claims 21-26 are introduced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating any of the recited dermatological conditions, does not reasonably provide enablement for a method of preventing said conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

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disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a therapeutic method for treatment or prevention of disease by administering a therapeutic agent to a patient. In the absence of an explicit definition in Applicant's specification, the claims are given their broadest reasonable interpretation. See MPEP 2111. Merriam-Webster's Collegiate Dictionary (reference included with PTO-892) defines "prevent" as meaning, "to deprive of power or hope of acting or succeeding," or "to keep from happening or existing." This definition is taken as representing the ordinary usage of the term "preventative". In order to deprive something of power or hope of acting or succeeding, the preventative agent must be completely effective. "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Merely slowing the onset of disease or making the disease less likely would still leave it with "power or hope of acting or succeeding," and thus not qualify as prevention.

The state of the prior art: Dermatological compositions comprising proanthocyanidin are known in the art to be useful as therapeutics for the treatment of

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certain dermatological disorders. They are not known to completely prevent the recited disorders, in the sense of completely removing any chance of future occurrence.

In general, preventing a disorder, according to the definition of prevention given below under the heading “breadth of the claims” is not possible as, in the absence of a cure which reverses the underlying cause, the disorder will ultimately progress to a point where tolerated doses of the therapeutic agent are no longer effective to retain the level of functioning experienced before the onset of disease.

It should also be noted that, for the purpose of claim interpretation, references to “prevention” in the art are not considered relevant to interpretation of prevention in the claims unless Applicant’s disclosure explicitly defines the term “prevention” in the claims to mean a clinical outcome short of absolute perfection.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Prevention of a disease is not the same as treatment of said disease. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms? For example, will a metastatic cancer eventually adapt to overcome treatments directed to preventing it from metastasizing? Or will a case of osteoporosis or rheumatoid arthritis ultimately progress to a point where symptoms develop regardless of which therapy is administered.

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many therapies which are suitable for short-term relief of symptoms are not suitable for lifelong prevention of disease. For example, antibiotics, chemotherapeutics, and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer.

The Breadth of the claims: In the absence of an explicit definition in Applicant's specification, "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Any therapy which merely reduces the number or severity of symptoms, or which is effective for a period shorter than the subject's remaining lifespan, is considered to be ineffective at preventing a disorder.

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The amount of direction or guidance presented: No guidance is given in the specification suggesting any reason to believe that administration of a dermatological composition containing proanthocyanidin or any other ingredients is capable of completely and totally preventing dermatitis, xerosis, psoriasis, or any of the other recited disorders.

The presence or absence of working examples: No working examples are given. Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: As mentioned above, the short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. In particular, one skilled in the art, in order to practice the invention for prevention of disease, would need to know whether the preventative effect remains potent over the long term.

In order to answer these questions in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term animal tests, preferably over a period of years, preferably involving a relatively long-lived experimental animal such as dogs or monkeys, or a human clinical trial. Animal experiments include, along with induction of the disease state, administration of the

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potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Administering the claimed compounds for a period of years to a suitable subject population is an undue amount of experimentation needed in order to practice the full range of the claimed invention. As prevention in the full sense is an extremely high bar for any clinical outcome, there is no reason to believe that the therapy would be successful, and any actual success would be a surprising and unpredictable result.

Genentech, 108 F.3d at 1366, states that, “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion.” And “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of working examples, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of disease.

Claims 13, 15, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating atopic dermatitis, allergic contact dermatitis, seborrheic dermatitis, radiation dermatitis, psoriasis, xerosis, and atopy, does not reasonably provide enablement for a method of treating any dermatological disease or disorder whatsoever. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a therapeutic method comprising administering a composition to a patient. In order to be enabled for making and using the disorder, one skilled in the art must reasonably be able to practice the invention in such a way as to successfully treat any of the diseases within the scope of the claims.

The state of the prior art: The prior art is aware of a wide variety of dermatological disorders. According to the Merck Manual of Diagnosis and Therapy, Seventeenth Edition, (Reference included with PTO-892) skin disorders known in the art include dermatitis, bacterial, viral, fungal, and parasitic infections, follicle disorders, inflammatory disorders, sunlight or radiation disorders, pigmentation disorders, cornification disorders, and benign and malignant tumors, all of which possess different pathogenic mechanisms and are amenable to different treatments. (pp. 777-778)

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Therapeutic agents used to treat these diseases include various different types such as cleansing agents, protective agents, anti-infective agents, analgesics, and antiinflammatory agents, for example. (pp. 783-786) No single therapeutic agents is known to relieve all dermatological disorders or symptoms, or to be broadly useful against all dermatological disorders, and the prior art does not provide any expectation that such a broad-spectrum treatment would exist.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: When treating a disorder, one skilled in the art must adapt the treatment to the symptoms and causes of the particular disorder being treated. This requires that the therapeutic agent being used is one which has been validated in the art as being useful against whatever disorder is being treated. In the absence of specific data concerning both the disorder and the therapeutic agent, any action of the therapeutic agent against the disorder will be highly unpredictable.

The Breadth of the claims: The claimed invention is very broad, encompassing methods of treating any disorder of the skin by topically applying telmesteine.

The amount of direction or guidance presented: The specification suggests a number of diseases, such as dermatitis or psoriasis, that can be treated using telmesteine. The specification does not provide any reason for one skilled in the art to believe that telmesteine would be useful for treating all dermatological disorders, for example infective disorders or pigmentation disorders.

The presence or absence of working examples: No working examples are provided for the actual treatment of any disorders in a living subject.

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Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the broad-spectrum treatment of disease. See MPEP 2164.

The quantity of experimentation necessary: In order to reliably treat a disorder, one skilled in the art must have a reasonable expectation that the therapeutic agent being used will in fact be effective against said disorder. Because neither the prior art nor Applicant's own disclosure provides such an expectation for the broad-spectrum treatment of all possible dermatological disorders, one skilled in the art would have to evaluate the claimed treatment against a wide number of conditions, with no precedent in the prior art or the disclosure. Doing so would require an undue burden of unpredictable experimentation.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of guidance or working examples, Applicants fail to provide information sufficient to practice the claimed invention for all possible dermatological disorders.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 13-15, 18, 19, 21-23, 25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Mastrodonato et al. (PCT international publication WO03/084553, reference of record with PTO-1449)

Mastrodonato et al. discloses topical compositions comprising telmesteine, for treating inflammatory conditions of the skin such as atopic dermatitis, allergic contact dermatitis, seborrheic dermatitis, radiation dermatitis, psoriasis, xerosis, and atopia. (p. 1 lines 1-8) These compositions can be in the form of a cream, gel, lotion, suspension, spray, ointment, or foam. (p. 5 lines 7-8) Antioxidants such as tocopherol and ascorbate derivatives are included as well. (p. 4 lines 2-7) These are reasonably considered to be stabilizing agents because their antioxidant activity stabilizes oxidizable molecules against oxidation. Specific examples of compositions are disclosed comprising various ingredients including telmesteine, sodium hyaluronate, ethylhexyl palmitate, pentylene glycol, arachidyl alcohol, benzyl alcohol, alkyl glycosides, aglyceryl stearate, butylene glycol, capriloyl glycine, tocopherol acetate, carbomer, ethylhexyl glycerin, piroctone olamine, sodium tetrahexyldecyl ascorbate, propyl gallate, and water, which are the ingredients recited in instant claims 7-12. (pp. 6-13) Also note that C12-20 alkylglucoside is a surfactant according to the limitation of instant claim 5. Therefore Mastrodonato et al. anticipates the claimed invention.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

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under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 18, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianotti (Reference included in PTO-892) in view of Vinson et al. (Reference included with PTO-892) in view of Remington: The Science and Practice of Pharmacy, 20th Edition. (Reference included with PTO-892, Herein referred to as Remington)

Gianotti et al. discloses that telmesteine lowers the serum levels of lipoprotein A. (Abstract) Gianotti et al. does not disclose a composition comprising proanthocyanidin, glycyrrhetinic acid, and telmesteine, in the form of a cream, gel, lotion, suspension, spray, ointment, or foam, or a composition further comprising a wetting agent or phospholipids.

Remington discloses that systemically active drugs may be administered transdermally. (p. 917, right column, p. 918, left column) A transdermally delivered drug

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is applied to the skin and enters the body by this route. Penetrations enhancers including alcohols such as methanol, ethanol, or isopropanol, as well as surfactants can be added to a transdermal formulation to increase the absorption through the skin. (p. 842 left column table 44-3) note that alcohols including methanol, ethanol, and isopropanol are reasonably considered to be disinfectants as well as antibacterial and antifungal agents because they can be used to kill infectious agents such as bacteria and fungi.

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate telmesteine as a cream, gel, lotion, suspension, spray, ointment, or foam, and to add ordinary topically acceptable carriers, diluents, or excipients such as a wetting agent or a phospholipid. One of ordinary skill in the art would have been motivated to formulate the composition in this manner in order to make it suitable for transdermal administration. One of ordinary skill in the art would have reasonably expected success because determining the exact route of administration and adding ordinary, well known inactive ingredients to a known composition is well within the ordinary and routine level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 7, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrodonato et al. (Reference included with PTO-1449)

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The disclosure of Mastrodonato et al. is discussed above. Mastrodonato et al. does not disclose compositions having the exact amounts of each active ingredient recited in claims 7, 9, and 11.

It would have been obvious to one of ordinary skill in the art at the time of the invention to vary the specific amounts of the individual active ingredients in the compositions of Mastrodonato et al. to arrive at the claimed compositions. One of ordinary skill in the art would have recognized that the amounts of the various ingredients could be optimized to produce a composition suitable for the intended purpose. Doing so is well within the ordinary and routine level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 13, 14, 22, and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 13, and 14 of U.S. Patent No. 7262180. (Cited in PTO-892, herein referred to as '180) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3, 13, and 14 of '180 anticipate the claimed invention. Specifically, claims 1-3 are drawn to a cream ,gel, lotion, suspension, spray, ointment, or foam comprising telmesteine. Furthermore, claim 13 discloses additional active ingredients including alkyl glucosides which are surfactants. Finally claim 13 of '180 discloses a method for treating various disorders including those recited in instant claims 13 and 14 by administering said composition. Therefore the claims of '180 anticipate the claimed invention.

Claims 1-6, 13-15, and 22-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 28-30, and 37-39 of copending Application No. 11/358747. (Pre-grant publication 2006/0247183, cited in PTO-892, herein referred to as '747) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 25, 28-30, and 37-39 of '747 anticipate the claimed invention. Specifically, claims 25 and 28 of '747 claim a composition comprising telmesteine. Claims 29 and 30 of '747 introduce the same additional limitations found in instant claims 3-6 and 22-24. Claims

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37 and 38 disclose a method of treating diseases including dermatitis, psoriasis, and other conditions recited in instant claims 13 and 14. Claim 39 of '747 includes administering a second composition as recited in instant claim 15. Therefore the claims of '747 anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 13, 14, 22, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 15 of copending Application No. 11/841564. (Pre-grant publication 20080015155, cited in PTO-892, herein referred to as '564) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, and 15 of '564 anticipate the claimed invention. Specifically, claims 1 and 2 of '564 claim a composition comprising telmesteine that is a cream, gel, lotion, suspension, spray, ointment, or foam. Claim 15 discloses a method of treating diseases including dermatitis as recited in instant claims 13 and 14. Therefore the claims of '564 anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 13-15, and 22-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25,

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28-30, and 37-39 of copending Application No. 12/013244. (Pre-grant publication 2008/0144057, cited in PTO-892, herein referred to as '244) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 25, 28-30, and 37-39 of '244 anticipate the claimed invention. Specifically, claims 25 and 28 of '244 claim a composition comprising telmestaine. Claims 29 and 30 of '244 introduce the same additional limitations found in instant claims 3-6 and 22-24. Claims 37 and 38 disclose a method of treating diseases including dermatitis, psoriasis, and other conditions recited in instant claims 13 and 14. Claim 39 of '244 includes administering a second composition as recited in instant claim 15. Therefore the claims of '244 anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-7, 9, 11, 13-15, 18, 19, and 21-26 are rejected. Claims 8, 10, and 12 are seen to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
4/3/2009